UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Docket No.: 1:20-cv-03495(FB)(SJB)

GOVERNMENT EMPLOYEES INSURANCE COMPANY, GEICO INDEMNITY COMPANY, GEICO GENERAL INSURANCE COMPANY, And GEICO CASUALTY COMPANY,

Plaintiffs,

-against-

ALEXANDR ZAITSEV, M.D., et al.,

Defendants.

EXPERT DISCLOSURE PURSUANT TO FRCP 26(a){2)

James Murphy, M.D., MMM, DFASM

Defendants, by and through their attorneys, Schwartz, Conroy & Hack, P.C., hereby provide this disclosure pursuant to FRCP 26(a)(2):

1. Plaintiffs retained the following expert to present testimony under FRE 702,703, and 705.

James Murphy, M.D., MMM, DFASM
Murphy Pain Center (office)
720 Rolling Creek Drive, Suite 101
New Albany, Indiana 47150
Area of Expertise: Pain Management-Medicine and Addiction Medicine

2. Annexed hereto as **Exhibit "A",** is a copy of Dr. Murphy's expert report.

3. A copy of Dr. Murphy's Curriculum Vitae is incorporated in Exhibit "A".

4. A list of cases in which Dr. Murphy testified is incorporated in Exhibit "A".

5. Dr. Murphy has been compensated to date $14,000 and compensation is the rate of $500 an hour.

6. The opinions set forth in Dr. Murphy's report will be supported by the

information provided in his expert report. and the basis and reasons for those opinions will be supported by the facts and data considered by Dr. Murphy in forming those opinions. Exhibit "A."

Dated: Garden City, New York
March 20, 2023

SCHWARTZ, CONROY & HACK, PC

By: */s/Matthew J. Conroy*
Matthew J. Conroy, Esq.
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To:
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EXHIBIT A

Murphy Pain Center

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James Patrick Murphy, M.D.
Medical Director
Murphy Pain Center

March 20, 2023

Robert Hewitt, Esq.
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666 Old Country Road, Suite 900
Garden City, New York 11530-2020

RE: GOVERNMENT EMPLOYEES INSURANCE COMPANY, GEICO INDEMNITY COMPANY, GEICO GENERAL INSURANCE COMPANY, and GEICO CASUALTY COMPANY, Plaintiffs,

-Against -

ALEXANDR ZAITSEV, M.D., METROPOLITAN INTERVENTIONAL MEDICAL SERVICES, P.C., ANTHONY BENEVENGA, CHARLES G. NICOLA, D.C., RIDGEWOOD DIAGNOSTIC LABORATORY, L.L.C., TRI- STATE MULTI-SPECIALTY MEDICAL SERVICES, P.C., RIVERSIDE MEDICAL SERVICES, P.C., KRISTAPPA SANGAVARAM, M.D., EUGENE GORMAN, M.D., BOGDAN NEGREA, M.D., ANTONIO CICCONE, D.O., STELLA AMANZE, P.A., FRIDA ISAKOV, P.A., LUCKNIE OVINCY, P.A., EMILY BAKERMAN, N.P., MELISSA EVANS, N.P., MINI MATHEW, N.P., ANGELA PULLOCK, N.P., LINDA SANTA MARIA, N.P., and RIVKA WEISS, N.P.,

Defendants.

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK
Docket No.: 1:20-cv-03495- FB-SJB

Dear Robert Hewitt, Esq.,

PURPOSE OF MY REPORT

You have asked me to write a report regarding the Defendants' medical necessity, appropriateness, and overall clinical practice with regard to drug screening of their patients, and rebutting the opinions contained in the expert reports of Elizabeth Spratt, M.S., F-ABFT ("Spratt") and Naum Shaparin, M.D. ("Shaparin"). This report contains my opinions, the basis

and reasons for my opinions, and information considered by me in forming my opinions. In sum, the Defendants' policies, procedures, and utilization of drug screens in caring for their patients, were reasonable, medically necessary, in the usual course of professional practice, for a legitimate medical purpose, and consistent with the applicable standard of care. Moreover, the conclusions reached by Shaparin and Spratt to the contrary, as discussed below, are erroneous. The drug testing ordered was supported by appropriate protocols, and consistent with acceptable standards of care, contrary to Shaparin's and Spratt's opinion.

RELEVANT EXPERIENCE

I attended the University of Louisville School of Medicine and graduated in 1985. After medical school, I did my internship in the Department of Psychiatry at the Naval Medical Center in San Diego and, upon completion, served as a General Medical Officer at the Naval Training Center in San Diego for six months. After this time in San Diego, I attended training at the Naval Aerospace Medical Institute at NAS Pensacola, graduated, and became a U.S. Navy Flight Surgeon. I served as a Flight Surgeon from 1987-1989, deploying to the Western Pacific onboard the aircraft carrier U.S.S. Enterprise as the Attack Flight Surgeon for Carrier Air Wing Eleven, stationed at NAS Lemoore, California.

Upon completing my tour of active duty, I returned to the University of Louisville and did my anesthesiology residency from 1989-1992. Upon completion of my residency I moved to Elizabethtown, Kentucky where, from 1992-1997, I worked as an anesthesiologist at Hardin Memorial Hospital for the anesthesiology company that I founded. I left my Elizabethtown anesthesiology practice in 1997 to attend subspecialty training in pain management. In 1998, I completed my fellowship in pain management at the Mayo Clinic in Rochester, Minnesota. During my fellowship, I was promoted to a faculty position and served as an Associate Consultant and Instructor of Anesthesiology for the Mayo Medical School.

After my Mayo Clinic experience, I returned to my hometown of Louisville, Kentucky where, for over two decades I have treated patients using a multidisciplinary approach that has included, where appropriate, the prescribing of controlled substances as well as an extensive range of interventional pain treatment procedures. I continue to practice full time, and, like the Defendants in this case, I utilize drug screening as a risk mitigation strategy in caring for my patients. My office is located across the river from Louisville in New Albany, Indiana, and I am licensed to practice medicine in Indiana and Kentucky. In addition to caring for patients with

chronic pain, I am also an addiction medicine specialist and treat patients with substance use disorders.

Over the years, in service to the Mayo Medical School, the University of Louisville, and the American Society of Regional Anesthesia, I have instructed medical students, resident physicians, and practicing physicians on the reasonableness, medical necessity, and utility of pain care treatments, addiction treatment, and risk mitigation strategies. I also have years of experience as an independent physician reviewer responsible for determining the reasonableness and medical necessity of interventional pain procedures, prescriptions, and risk mitigation strategies such as urine drug screens.

I am triple board-certified in Anesthesiology, Pain Medicine, and Addiction Medicine. I also earned a Master of Medical Management (MMM) degree from the University of Southern California's Marshall School of Business. Since 2004, I have continued to serve the University of Louisville School of Medicine as an Assistant Clinical Professor in the Department of Anesthesiology and Perioperative Medicine. In 2021, I was awarded the designation of Distinguished Fellow (DFASAM) by the American Society of Addiction Medicine. I am the immediate past president of the Kentucky Society of Addiction Medicine. I serve on the board of directors of the Kentucky Harm Reduction Coalition. I am the American Society of Addiction Medicine (ASAM) Region X Director. I also represent ASAM on the American Medical Association's Substance Use and Pain Care Task Force.

I have given lectures and conducted numerous seminars regarding legitimate and appropriate risk mitigation strategies. Over the years, I have worked closely with the medical licensing boards of Kentucky and Indiana on treatment issues, and both boards currently feature on their websites prescribing guidance I have authored. Numerous articles on pain management treatment and monitoring principles written by me, or with my co-authorship, have been published in regional and national medical journals. Since 2016, I have testified approximately twenty times in federal court as an expert witness regarding pain and/or addiction issues (including the proper utilization of risk mitigation strategies) and have never been disqualified as an expert witness.

The opinions expressed in this report are my own, are to a reasonable degree of medical certainty, and should not be ascribed to any other individual or organization. As a matter of policy, I reserve the right to amend this report should any additional pertinent information and/or data be made available to me.

MATERIALS REVIEWED

From counsel, I was provided files containing medical records, prescription data, and other items related to patients of the Defendants with the initials: WV, IE, MR, SA. I reviewed a report by Elizabeth Spratt, M.S., F-ABFT, with exhibits and a report by Naum Shaparin, M.D with exhibits. I reviewed the Amended Complaint, Docket No.: 1:20-cv-03495- FB-SJB. I reviewed transcripts from deposition testimony by Alexandr Zaitsev. I reviewed transcripts from deposition testimony by Eugene Gorman. A list of my cited references is included at the end of my report. I received and/or invoiced $14,000 total for a preliminary review, my review and analysis of the documents discussed herein, and the preparation of this report.

BASIS OF OPINIONS

The American Medical Association's Code of Medical Ethics characterizes the practice of medicine this way (Ref: CODE):

> *The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering.*

The AMA's Code notes that a physician-patient relationship is established "when a physician serves a patient's medical needs." When a patient has a medical need, whether it be subjective (e.g., pain), or objective (e.g., inflammation, nerve entrapment, arthritis, etc.) a medical necessity exists (Ref: CODE). Actions by the physician which are intended to help treat a patient's medical condition or conditions (e.g., urine drug screens) are serving a legitimate medical purpose, and are therefore, medically necessary.

Urine drug testing (UDT) in clinical practice should not be used in a punitive manner but should be used in the context of other clinical information to inform and improve patient care, i.e., UDT is a therapeutic act, not a punitive act (Ref: CDC22). The Defendants use of drug testing (UDT) was clearly aimed at providing therapeutic benefit to their patients.

Our nation's expanding overdose crisis mandates increased caution when prescribing controlled substances for pain or any other condition. Data from the CDCs National Center for Health Statistics indicated that there were over 100,000 drug overdose deaths in the United States during the 12-month period ending in April 2021, an increase of 28.5% from the 78,056 deaths during the same period the year before (Ref: PPJ). Importantly, overdose deaths from synthetic opioids (primarily fentanyl) and psychostimulants such as methamphetamine also

increased in the 12-month period ending in April 2021. Cocaine deaths also increased, as did deaths from natural and semi-synthetic opioids, such as prescription pain medications. Heroin deaths continued at a high level. Illicitly manufactured fentanyls (IMFs) are now widespread in white powder heroin markets, increasingly pressed into counterfeit pills resembling oxycodone, alprazolam, or other prescription drugs, and are expanding into new markets. This may have large consequences as overdoses related to illicit fentanyl will show up as prescription opioids including oxycodone, alprazolam, or other prescription drugs. In addition, approximately forty percent of IMF-involved deaths also involved a stimulant.

The opioid epidemic waves have been described in various ways. The first wave began with increased prescribing of opioids in the 1990s, and the second wave beginning in 2010 with a rapid increase in overdose deaths involving heroin. A third wave came near the beginning of 2013 with a significant increase in overdose deaths involving synthetic opioids, particularly those involving illicit fentanyl. Subsequent assessment has led to the fourth wave of the opioid epidemic driven by polysubstance use and stimulants. The primary drivers of increasing overdose deaths continue to be fentanyl, heroin, cocaine and psychostimulants while prescription opioid deaths have declined to the same or below the levels of cocaine, heroin, and methamphetamine.

Overall illicit drug use, opioid abuse, and noncompliance of opioids is significant in patients who utilize controlled substances to treat their pain. Substance misuse has been documented at over 30% in patients on opioid therapy (Ref: VA22). And as high as 60% in Medicaid patients (Ref: MAN). Concurrent use of opioid pain medications with other opioid pain medications, benzodiazepines, or heroin can increase patients' risk for overdose. Urine drug tests can provide information about drug use that is not reported by the patient. In addition, urine drug tests can assist clinicians in identifying when patients are not taking opioids prescribed for them, which might in some cases indicate diversion or other clinically important issues such as difficulties with adverse effects (Ref: CDC).

The inaccuracies inherent to patient self-reporting coupled with the evident mortality and morbidity to the treated patients, their families, and urine drug testing is a clinically recommended method of examining for patient substance misuse and adherence to the prescribed regimen (Ref: VA22). UDT can also help in the development of trust within the patient-provider relationship. It is critical that the UDT and confirmatory testing be done in a timely, accurate, and easily available manner to assure the prescribers, patients, and public that safety, fairness,

and trust are being addressed. Ideally, clinicians would only test for substances for which results could affect patient management. However, it can be challenging for clinicians in many settings to tailor widely used toxicology panels to include the specific substances most relevant to clinical decisions for their patient. Toxicology testing costs are not always covered fully by insurance and can be a burden for patients, and clinician time is needed to interpret, confirm, and communicate results Ref: CDC22).

TYPES OF URINE DRUG TESTING

The most commonly drug-tested bodily specimen is urine (Ref: CDC22). There are three main types of UDT currently being utilized in clinical settings: (1) immunoassay, (2) gas chromatography-mass spectrometry (GCMS) confirmatory testing, and (3) liquid chromatography-mass spectrometry (LCMS) confirmatory testing. Immunoassay screening is inexpensive, fast, and widely available. However, there are a number of drawbacks to using this test alone. There is a higher potential for false positives and negatives as well as a lack of specificity of the actual opiate or benzodiazepine being tested. A clinician must be careful not to place too much emphasis on screening drug tests, which are subject to a high rate of false-positive and false-negative results. UDT results, especially results of screening tests with suspect accuracy, can also be subject to misinterpretation and may even be associated with practices that can harm patients (e.g., stigmatization, inappropriate termination from care). Thus, it is never wrong to send a presumptive screening test on to the lab for definitive confirmatory testing – assuming cost to the patient is not a barrier that merits consideration, which it would not be in the No-Fault setting.

Below is a table from the 2022 VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain which summarizes many of the agents that can contribute to false positive results on a screening immunoassay urine drug test (Ref: VA22):

Agent	Summary of Agents Potentially Contributing to False Positives	
Marijuana metabolites	• dronabinol • efavirenz • proton pump inhibitors	• NSAIDs[a] • hemp foods: tea, oil[b]
Cocaine metabolites	• coca leaf teas	• topical anesthetics containing cocaine
Opioid metabolites (229, 231-233)	• dextromethorphan • fluoroquinolones • verapamil • nalmefene • naloxone • diphenhydramine	• verapamil • papaverine • quinine • poppy seeds • poppy oil • rifampin
Amphetamines/ Methamphetamine (high rate of false positives)	• amantadine • benzphetamine • brompheniramine • bupropion • chlorpromazine • desipramine • dextroamphetamine • doxepin • ephedrine • trimipramine • diphenhydramine • papaverine • phentermine • phenylephrine • fluoxetine • verapamil	• isometheptene • isoxsuprine • labetalol • l-methamphetamine (OTC nasal inhaler) • methylphenidate • MDMA • nalmedfene • naloxone • propanolamine • promethazine • pseudoephedrine • ranitidine • selegiline • thioridazine • trazodone • trimethobenzamine
Benzodiazepines	• oxaprozin	• sertraline
Barbiturates	• ibuprofen • phenytoin	• naproxen • primidone
Methadone	• chlorpromazine • clomipramine • diphenhydramine • quetiapine	• doxylamine • ibuprofen • thioridazine • verapamil
Alcohol	• mouthwash • use of hand sanitizers • nonalcoholic beer or wine • communion wine	• food cooked with alcohol • short-chain alcohols • OTC cough products (isopropyl alcohol)
Buprenorphine/Naloxone metabolites	• naloxone-3-glucuronide • noroxymorphone	• naloxol

[a] Detection time for most drugs in urine is 1 – 3 days

[b] Long-term use of lipid-soluble drugs (THC, diazepam, ketamine) can be detected for a longer period

Abbreviations: NSAIDs: non-steroidal anti-inflammatory drugs; MDMA: 3,4-methylenedioxy-methamphetamine; OTC: over the counter; THC: tetrahydrocannabinol

GCMS and LCMS are highly sensitive and specific and is more expensive than immunoassay. LCMS and GCMS can confirm a large number of medications, substances, and drugs at one time and is useful in mitigating risks for patients. The following table is from the 2022 VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic

Pain and summarizes many of the substances for which UDTs commonly test along with some salient clinical considerations.

Interpreting Urine Toxicology Screening

Drug or Class		Expected Results	Considerations
Non-opioids	Alcohol	Alcohol	• Testing for ethanol metabolites, ethyl glucuronide, or ethyl sulfate can identify alcohol up to 80 hr after consumption
	Amphetamines	**Immunoassay**–Amphetamines, methamphetamines, or MDMA **Confirmatory** – Amphetamines, methamphetamines, or MDMA	• Immunoassay tests are highly cross-reactive; therefore, confirmatory testing is required and can identify which amphetamine is present
	Benzodiazepines	**Immunoassay** – Unconjugated oxazepam or its metabolites **Confirmatory** – Alprazolam, diazepam, clonazepam, lorazepam, etc.	• Immunoassays for benzodiazepines have a 28% overall false negative rate • Confirmatory testing is needed when use is expected or suspected (alprazolam, clonazepam, and lorazepam often not detected by immunoassay)
	Barbiturates	**Immunoassay** – Barbiturates	• N/A
	Cocaine metabolites	**Immunoassay** – Cocaine or benzoylecgonine	• Cocaine's primary metabolite, benzoylecgonine, has low cross-reactivity with other substances and is highly predictive of cocaine use • A positive result should be interpreted as recent exposure to cocaine
Opioids or "Opiates" – Natural (From Opium)	Codeine (Tylenol #2,3/4)	**Opiates Immunoassay** – Positive **Confirmatory** – Codeine, possibly morphine and hydrocodone	• Immunoassays for "opiates" are responsive to morphine and codeine but do not distinguish which • Codeine is metabolized to morphine and small quantities of hydrocodone
	Morphine (Avinza, Embeda, MS Contin, Kadian)	**Opiates Immunoassay** – Positive **Confirmatory** – Morphine, possibly hydromorphone	• Immunoassays for "opiates" are responsive to morphine and codeine but do not distinguish which • Morphine (<10%) may be metabolized to hydromorphone
	Heroin	**Opiates Immunoassay** – Positive **Confirmatory** – Heroin (6-MAM), morphine, possibly codeine	• 6-MAM is pathognomonic for heroin use, detection 12 – 24 hr • Heroin is metabolized to morphine

Drug or Class		Expected Results	Considerations
Opioids – Semisynthetic (Derived from Opium)	Hydrocodone (Lorcet, Lortab, Norco, Vicodin)	**Opiates Immunoassay** – Positive **Confirmatory** – Hydrocodone, possibly hydromorphone, norhydrocodone, or dihydrocodeine (236-240)	• "Opiates" immunoassay may detect semisynthetic opioids • Hydrocodone >hydromorphone >oxycodone • Negative result does not exclude use and confirmatory testing (GCMS) is required • Hydrocodone is metabolized in small amounts to hydromorphone, both may be found in urine • Oxycodone is metabolized to oxymorphone, both may be found in urine • Hydromorphone and oxymorphone use does not result in positive screens for hydrocodone and oxycodone, respectively
	Hydromorphone (Dilaudid, Exalgo)	**Opiates Immunoassay** – May be positive **Confirmatory** – Hydromorphone	
	Oxycodone (Roxicet, OxyContin)	**Opiates Immunoassay** – May be positive **Oxycodone Immunoassay** – Positive **Confirmatory** – Oxycodone possibly oxymorphone, noroxycodone (236-240)	
	Oxymorphone (Opana)	**Oxycodone Immunoassay** – Positive **Confirmatory** – Oxymorphone, noroxymorphone (236-240)	
Opioids – Synthetic (Man-made)	Buprenorphine	**Immunoassay** – Buprenorphine **LCMS, GCMS** – Buprenorphine, norbuprenorphine	• Current "opiates" immunoassays do not detect synthetic opioids • Confirmatory testing (GCMS or LCMS) is needed
	Fentanyl	**GCMS** – Fentanyl, norfentanyl, carfentanyl, sufentanyl	
	Meperidine (Demerol)	**GCMS** – Normeperidine, possibly meperidine	
	Methadone (Methadose)	**Methadone Immunoassay** – Positive **GCMS** – Methadone, EDDP	
	Tramadol	**LCMS, GCMS** – tramadol, O-desmethyl tramadol[b]	
	Novel synthetic opioids	**MT45** **U-47700**	

[a] Each facility may have its own order sets and lab policies and procedures; contact your lab for additional details

[b] For more information on tramadol, access Lexicomp Online

Abbreviations: 6-MAM: 6-monoacetylmorpine; EDDP: 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine; GCMS: gas chromatography-mass spectrometry; LCMS: liquid chromatography-mass spectrometry; MDMA: 3,4- methylenedioxy-methamphetamine

Drug testing is part of the clinician's diagnostic process – a process which is patient-centered, continual, never completed, and never certain (Ref: NAS). Drug testing provides data points indicative of past behavior that can be used in an effort to predict future behavior and hopefully modify future behavior to achieve beneficial outcomes. While, many clinical guidelines offer advice on how one might justify not obtaining a drug screen at a particular visit, these guidelines do not prohibit obtaining frequent drug screens if the treating clinician decides that the benefit of frequent testing outweighs the potential harms (e.g., costs). For example, I practice in Indiana, where the prescribing regulations clearly state: "At any time the physician determines that it is medically necessary, whether at the outset of an opioid treatment plan, or any time thereafter, a physician prescribing opioids for a patient shall perform or order a drug monitoring test, which must include a confirmatory test using a method selective enough to differentiate individual drugs within a drug class, on the patient." (Ref: IND). And the Federation of State Medical Boards was very also very clear regarding who was responsible for deciding how, when, and how often a test (e.g., drug screen) should be ordered on a patient (Ref: FSMB):

> *The tests performed, questions asked, and evaluations made should be tailored to the patient as guided by the physician's clinical judgment.*

And in their updated 2022 Guideline, the CDC said clinicians should consider toxicology screening results as potentially useful data for all patients (Ref: CDC22), which contradicts Shaparin's opinion regarding drug testing being limited to certain clinical justifications only or Spratt's opinion that the tests were ordered without justification.

OPIOIDS AND RISK MITIGATION

Opioids along and other controlled substances can be effective and are widely utilized in the treatment of pain. Clinicians should not necessarily choose controlled substances (e.g., opioids) as a first-line treatment for most painful conditions, however controlled substances can become a necessary mode of therapy in some cases. Thus, strategies to mitigate risks associated with opioid prescribing warrant consideration when treating patients with complaints of pain. UDT is one such risk evaluation and mitigation strategy (REMS). Regulatory bodies that govern the practice of medicine expect prescribers to incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances (Ref: FUS). In their 2016 Guideline for Prescribing Opioids for Chronic Pain the CDC said that urine drug tests can

assist clinicians in identifying when patients are not taking opioids prescribed for them, which might in some cases indicate diversion or other clinically important issues such as difficulties with adverse effects. The CDC also said that evidence review found that urine drug testing can provide useful information about patients assumed not to be using unreported drugs. The CDC note that their experts agreed that prior to starting opioids for chronic pain and periodically during opioid therapy, clinicians should use urine drug testing to assess for prescribed opioids as well as other controlled substances and illicit drugs that increase risk for overdose when combined with opioids, including nonprescribed opioids, benzodiazepines, and heroin. Furthermore, the CDC noted that routine use of urine drug tests with standardized policies at the practice or clinic level might destigmatize their use and pointed out that some clinics obtain a urine specimen at every visit (Ref: CDC). This makes Spratt's opinion that routine ordering of such tests was inappropriate to be incorrect.

UNIVERSAL PRECAUTIONS IN PAIN MANAGEMENT

Creating a UDT policy that is applicable universally and consistently with all patients assists to de-stigmatize UDT and can potentially convince patients that it has nothing to do with an individual patient or their trustworthiness. Consequently, the practice can explain to patients that drug testing is a routine procedure for all patients starting or maintained on opioid therapy and it is an important tool for monitoring the safety of opioid therapy. The UDT not only provides adherence monitoring, but it is also a monitoring tool for safety (Ref: AROP). Spratt and Shaparin's opinions to the contrary are incorrect, as it goes against the reasons for a UDT policy. Because the fear of addiction is one of the barriers to opioid pain management, the result can be under treatment or even nontreatment of moderate to pain severe enough to require opioid treatment. Unfortunately, there are no signs pathognomonic of substance use disorders. Addiction is a brain disease in which the diagnosis is most often made prospectively over time by monitoring the patient's behavior and the ability to stay within a mutually agreed upon treatment plan. In view of the fact there is no definite test or physical sign that will predict which patient will do well on a therapeutic trial of opioids for pain, it makes sense to take a universal precautions approach to all pain patients.

Pain is the most common complaint for patients seeking healthcare services. Approximately 50–70 million people in the United States are undertreated or not treated for painful conditions. The goal of pain treatment is to decrease pain and improve function while

monitoring for any adverse side effects . If this goal is not achieved by non-opioid and adjunctive analgesics, opioids may be indicated. Data suggest that 3–16% of the American population have addictive disorders. Therefore, based on these statistics, as many as 5–7 million patients with the disease of addiction also have pain. In fact, when studying pain in certain subsets of the general population, the incidence may be considerably greater.

By adopting a universal precautions approach to the management of all chronic pain patients, regardless of pharmacologic status, stigma is reduced, patient care is improved, and overall risk is contained. Careful application of this approach will greatly assist in the identification and interpretation of aberrant behavior and, where they exist, the diagnosis of underlying addictive disorders. In those found to have, or be at risk of having complicating addictive disorders, treatment plans can be adjusted on a patient-by-patient basis. Adopting a universal precautions approach to the management of chronic pain will be an important step in raising the standard of care in this often complex patient population (Ref: UNI). These reasons for a UDT are ignored by Spratt and Shaparin.

STANDING ORDERS

Standing orders are written protocols that authorize designated members of the health care team (e.g., nurses or medical assistants) to complete certain clinical tasks without having to first obtain a physician order. Using standing orders is an established way to redistribute the physician workload across the care team, allowing the physician to focus on acute care and more complex medical decision making while ensuring that more routine patient needs are met by others. Standing orders can increase the delivery of routine services including (e.g., drug testing). Implemented standing orders can helped a practice improve patient care and clinical efficiency. Once firmly established in the clinic workflow, standing orders can increase not only the quality of care but also clinical efficiency (Ref: SOR). Relying only on dysfunctional behaviors to trigger a urine drug test will miss more than 50% of drug abusers (Ref: KATZ). Therefore, Shazain is incorrect when he opines that Tristate and Riverside's urine drug testing ordering practices were inconsistent with the standard of care because they were routinely ordered and part of a protocol.

PROCESS

In the usual course of professional practice, a physician obtains a medical evaluation and a collection of relevant clinical history commensurate with the presentation of the patient in an effort to establish diagnoses and identify underlying conditions or contra-indications to proposed treatments (Ref: FSMT). Simply put, physicians evaluate and treat. This is the physician's process and has been true for millennia. The physician's process begins with an effort to establish the diagnosis. In 2015, the National Academies of Medicine, our nation's foremost advisory agency on medical issues, published definitive guidance in their book *Improving Diagnosis in Health Care*. In addition to providing an overview of how a diagnosis is determined, NAM's text provided an overview of the actions undertaken by a physician working toward a diagnosis in the usual course of professional practice. NAM confirmed what over thirty years of practice have taught me—that a physician's diagnostic process is a complex activity that involves information gathering and clinical reasoning specific to the individual patient. This process is ongoing, is continually modified by new information, is never fully completed, and is not hindered by a requirement for complete diagnostic certainty (Ref: NAS).

Initially, a patient experiencing a medical problem seeks care from a physician. Then information is gathered, integrated, and interpreted by the physician in an attempt at formulating the best estimation of a "working diagnosis." Physicians do not need to obtain diagnostic certainty prior to initiating treatment. Gathering clinical history to make a diagnosis is often an iterative process, and the physician's course of action is dependent upon the relationship between the clinician and patient, and in consideration of the circumstances and unique needs of each patient (Ref: CDC, FSMT). Information-gathering approaches can be employed at different times, and diagnostic information can be obtained in different orders from a variety of sources. It is a continuous process. Ways that physicians gather information vary and can include activities such as: taking a history, conducting a physical exam, performing tests, or consulting other clinicians. These are not the only methods a physician can use to gather information, nor is each method mandatory.

After a diagnostic effort, treatment follows. The treatment, or plan of care, is the result of intuitive reasoning and clinical judgment by the physician. The process by which the plan of care is conceived is biased by specific characteristics inherent to both the patient and the physician. Thus, decision-making is fluid and dependent on individual physician and patient circumstances, e.g., person, place, and time. Consequently, there is no singular best logic, manner, method, or

sequence of events that can encompass the full range of acceptable actions. Ultimately, the goal in treatment is a right and helpful action for the patient – a goal which while always desirable, is not always achievable – and the treatment plan comes to represent merely a singular point along the continuum in a physician's course of professional practice with his or her patient (Ref: PEL).

SUMMARY

The Defendants served a population of patients, most of whom had complaints that included pain. Urine drug testing, both screening and definitive, is medically necessary for treating their patients' legitimate painful conditions in the usual course of professional practice. The Defendants' universal precautious approach to ordering drug tests was both reasonable and appropriate. The urine drug screens ordered by the Defendants were medically necessary, for a legitimate medical purpose, in the usual course of professional practice, and consistent with the applicable standard of care.

Respectfully,

James Patrick Murphy, MD, MMM, DFASAM

REFERENCES (in alphabetical order):

AROP - American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 - Guidance Pain Physician 2012; 15:S67-S116 • ISSN 1533-3159

CDC - CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

CDC22 - CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

CODE - AMA Code of Medical Ethics Opinion 1.1.1

FSMB - *Responsible Opioid Prescribing, Second Ed. Copyright 2012, trademarked by the Federation of State Medical Boards Research and Education Foundation and published with support from the Substance Abuse and Mental Health Services Administration, U.S. Dept. of Health and Human Services.*

FSMT - THE APPROPRIATE USE OF TELEMEDICINE TECHNOLOGIES IN THE PRACTICE OF MEDICINE - *Adopted by the FSMB House of Delegates, April 2022*

FUS - *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Federation of State Medical Boards of the United States, Inc. Adopted May 2004. Available at: http://www.fsmb.org .

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MAN – Prevalence of illicit drug use among individuals with chronic pain in the Commonwealth of Kentucky: an evaluation of patterns and trends. J Ky Med Assoc. 2005 Feb;103(2):55-62.

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PEL – *The Anatomy of Clinical Judgments, Some Notes on Right Reason and Right Action*, by Edmund D. Pellegrino

PPJ - Fourth Wave of Opioid (Illicit Drug) Overdose Deaths and Diminishing Access to Prescription Opioids and Interventional Techniques: Cause and Effect. Pain Physician: March/April 2022 25:97-124

SOR - Developing Standing Orders to Help Your Team Work
to the Highest Level *Fam Pract Manag.* 2018;25(3):13-16 www.aafp.org/fpm

UNI - Douglas L. Gourlay, MD, MSc, FRCPC, FASAM; Howard A. Heit, MD, FACP, FASAM
Medscape Neurology & Neurosurgery. 2005;7(1) ©2005 Medscape
Posted 04/28/2005

VA22 - VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain May 2022

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State licenses: Kentucky, Indiana

CERTIFICATIONS

American Board of Anesthesiology	
• Consultant in Anesthesiology (lifetime)	1994
• Subspecialty Certification in Pain Medicine	1996
• Subspecialty Recertification in Pain Medicine	2007
• Subspecialty Recertification in Pain Medicine	2017
• Maintenance of Certification in Pain Medicine	current
American Board of Pain Medicine (lifetime)	1997
American Board of Preventive Medicine	
• Subspecialty Certification in Addiction Medicine	2017
• Maintenance of Certification in Addiction Medicine	current
American Board of Addiction Medicine	2014
American Society of Addiction Medicine	2004

EDUCATION AND TRAINING

University of Southern California • Master of Medical Management (MMM)	2013
Mayo Clinic, Rochester, MN • Pain Management Fellowship	1998
University of Louisville • Anesthesiology Residency	1992
Naval Aerospace Medical Institute • Aerospace Medicine/Naval Flight Surgeon	1987
Naval Medical Center, San Diego, CA • Psychiatry Internship	1986
University of Louisville School of Medicine • Doctor of Medicine	1985
Westminster College, Fulton, MO • B.A. English	1981

ACADEMIC APPOINTMENTS

University of Louisville School of Medicine • Clinical Prof., Dept. of Anesthesiology	1998 - 2000 & 2004 - current
Mayo Medical School, Rochester, MN • Instructor of Anesthesiology	1997 - 1998

EMPLOYMENT

Murphy Pain Center • President and Medical Director	2000 - current
Mayo Clinic, Rochester, MN • Associate Consultant Physician	1997 - 1998
Heartland Anesthesiologists, Elizabethtown, KY • Anesthesiologist	1992 - 1997
United States Navy • Physician/Flight Surgeon/Anesthesiologist (Commander)	1982 – 2010

ASSOCIATIONS

American Medical Association (current)
American Society of Addiction Medicine
- Distinguished Fellow, American Society of Addiction Medicine (DFASAM 2021 - current)
- Director, Region X (2023 - current)
- Representing ASAM on AMA Substance Use and Pain Care Task Force: (2021 - current)
- Representing ASAM on AMA Pain Care Task Force: (2018 - 2021)

Kentucky Society of Addiction Medicine, President (2020 - 2022)
Kentucky Society of Addiction Medicine, Board of Directors (2020 - current)
Kentucky Harm Reduction Coalition, Board of Directors (2019 - current)
Kentucky Department for Public Health, Displaced Opioid Patient Work Group (2019 - current)
Greater Louisville Medical Society (President 2013 - 2014)
Kentucky Medical Association (Community Connector Leadership Program 2013)

jpm 3/12/2023

James Patrick Murphy, MD

Past Four Years Expert Witness Testimony at Trial or Deposition as of March 20, 2023

1. USA vs. WILLIAM LAWRENCE GREGORY SIEFERT, M.D. United States District Court, Eastern District of Kentucky, Northern Division, Covington. Case no. 2:21-cr-2-DLB-CJS. March 2023.
2. THE PEOPLE OF THE STATE OF NEW YORK vs. SUDIPT DESHMUKH. Supreme Court of the State of New York, County of Monroe. Indictment no. 2021-0059. March 2023.
3. USA vs. GILBERT R. GHEARING. U.S. District Court, Middle District of Tennessee, Northeastern Division. Case no. 2:19-00010. March 2023.
4. USA vs. CHARLES KISTLER, D.O. U.S. District Court, Southern District of Ohio, Eastern Division. Case no. 2:22-cr-00067-ALM. February 2023.
5. USA vs. FREEDA FLYNN. U.S. District Court, Southern District of Ohio, Eastern Division. Case no. 2:19-CR-208. January 2023.
6. USA vs. LESLY POMPY, MD. U.S. District Court, Eastern District of Michigan, Southern Division. Case no. 18-CR-20454. December 2022.
7. USA vs. THOMAS KELLER. U.S. District Court, Northern District of California, San Francisco. Case no. 3:18-cr-00462-VC. October 2022.
8. USA vs. DAVID W. SUETHOLZ, M.D. United States District Court, Eastern District of Kentucky, Northern Division, Covington. Case no. 2:21-CR-56-S-DLB. September 2022.
9. USA vs. SALOUMEH RAHBARVAFAEI, United States District Court for the Central District of California. Case no. 2:19-CR-00164. August 2022.
10. USA vs. THOMAS ROMANO. United States District Court, Southern District of Ohio, Eastern Division. Case no. 2:19-CR-00202-SDM. August 2022.
11. USA vs. DR. DAVID LEWIS, United States District Court, Eastern District of Michigan, Southern Division. Case no. 2:18-CR-20800
12. USA vs. HAU T. LA, United States District Court, Middle District of Tennessee, Nashville Division. Case no. 3:22-CR-00163. July 2022.
13. USA vs. HAU T. LA, United States District Court, Middle District of Tennessee, Nashville Division. Case no. 3:22-CR-00163. Daubert hearing. July 11, 2022.
14. DIANE RECTOR as personal representative of the estate of Lisa Mae Arndt, Plaintiff, vs. IDEAL OPTION PLLC, Defendant. CAUSE NO. CV-21-02-GF-BMM-JTJ. IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MONTANA GREAT FALLS DIVISION. Expert witness deposition: February 1, 2022.
15. USA vs. EUGENE SISCO III, United States District Court, Eastern District of Kentucky, Southern Division, Pikeville. Case number 7:20-CR-00023-REW-HAI. November 2021.
16. USA vs. JEFFREY CAMPBELL, United States District Court, Western District of Kentucky at Louisville. Case number 3:17CR-87-RGJ. May 2021.
17. USA vs. RICKY L. HOUDERSHELDT, D.O., Defendant. United States District Court for the Southern District of West Virginia, Huntington Division. CRIMINAL ACTION NO. 3:19- 00239 12-23-2020 (S.D.W. Va.). Sentencing trial. December 2020.
18. USA vs. KRISHAN KUMAR AGGARWAL and CHERIAN JOHN, Defendants. U.S. District Court for the Northern District of West Virginia. Case No. 5:18-cr-16-FPS. June 2019.
19. USA vs. NASHER-ALNEAM. U.S. DISTRICT COURT SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON. Case number 2:18-cr-151. April 2019.
20. USA vs. NASHER-ALNEAM. U.S. DISTRICT COURT SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON. Case number 2:18-cr-151. Daubert hearing. March 2019.

Publications by James Patrick Murphy, MD over the last ten years – updated January 17, 2023

Murphy, James P. *Medical Marijuana, The Elephant in the Room*. Louisville Medicine; Greater Louisville Medical Society. November 2021.

Addressing Obstacles to Evidence-Informed Pain Care. AMA Pain Care Task Force. AMA J Ethics. 2020;22(8):E709-717. doi: 10.1001/amajethics.2020.709. Link: https://journalofethics.ama-assn.org/article/addressing-obstacles-evidence-informed-pain-care/2020-08

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Murphy, James P. *Problem Solving*. Louisville Medicine; Greater Louisville Medical Society; Vol. 66; April 2019 (pg.6-7). Link: https://view.joomag.com/louisville-medicine-volume-66-issue-11/0140885001554128381?short&

Shields, L., Murphy, J. et al. (2019). *Decline in primary care providers' prescribing of Schedule II opioids following the implementation of federal and state guidelines*. Journal of Opioid Management, March-April 2019. 15(2):111-118, DOI: 10.5055/jom.2019.0492. Link: https://www.wmpllc.org/ojs/index.php/jom/article/view/2398

Murphy, JP. *Pain Management in Sickle Cell Disease*. Louisville Medicine. September 2018.

Murphy, JP. *5-Step initial approach to caring for the displaced pain patient on chronic opioid therapy.* Louisville Medicine. September 2018.

Murphy, JP. *Kentucky's updated controlled substances regulations.* Louisville Medicine. February 2018.

Murphy, JP. *From the President. Emerge again.* Louisville Medicine. May 2014.

Murphy, JP. *From the President. Snap on the gloves.* Louisville Medicine. April 2014.

Murphy, JP. *From the President. Failure becomes me.* Louisville Medicine. March 2014.

Murphy, JP. *Taking the Hoosier hysteria out of Indiana's new pain regulations.* Louisville Medicine. February 2014.

Murphy, JP. *From the President. This is a story about success.* Louisville Medicine. February 2014.

Murphy, JP. *From the President. How will you define yourself.* Louisville Medicine. January 2014.

Murphy, JP. *From the President.* Louisville Medicine. December 2013.

Murphy, JP. *From the President. Seeing Aye to Aye.* Louisville Medicine. November 2013.

Murphy, JP. *From the President. Conflluential Truth..* Louisville Medicine. October 2013.

Murphy, JP. *From the President. No margin, no mission.* Louisville Medicine. September 2013.